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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,137	10/03/2005	Kevin Jeffrey Barnham	18803	4715

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EXAMINER	
MURRAY, JEFFREY H	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
07/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,137	BARNHAM ET AL.	
	Examiner	Art Unit	
	JEFFREY H. MURRAY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 33-43* is/are pending in the application.

4a) Of the above claim(s) *1-21,23-25,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,26-28 and 35-39, 41,42* is/are rejected.

7)☒ Claim(s) *40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 22, 26-28, 35-43 are pending in this application. Claims 29-32 have been cancelled. Claims 1-21, 23-25, 33 and 34 have been withdrawn. This action is in response to the applicants' amendment after a non-final and reply filed on March 3, 2009.

Withdrawn Rejections/Objections

2. Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Claim Rejections - 35 USC § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 27-28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound, composition or a pharmaceutically acceptable salt thereof, does not reasonably provide enablement for any other compositions combined with "an inhibitor of the acetylcholinesterase active site, an antioxidant, an anti-inflammatory agent or an oestrogenic agent" not previously described. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

5. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make quinazolinones, applicant has provided no guidance, or provided any chemical or biological data and/or testing results of these particular compositions in combination with "an inhibitor of the acetylcholinesterase active site, an antioxidant, an anti-inflammatory agent or an oestrogenic agent" or a pharmaceutically acceptable salt thereof.

The quantity of experimentation needed to make or use the invention must be considered to determine if undue experimentation is present. Here applicants do not describe in any explicit detail what types of further active compounds have been combined with the compositions. These "inhibitors of the acetylcholinesterase active site, antioxidants, anti-inflammatory agents or oestrogenic agents" could cover a plethora of various disciplines as the "inhibitors of the acetylcholinesterase active site, antioxidants, anti-inflammatory agents or oestrogenic agents" terms are undefined.

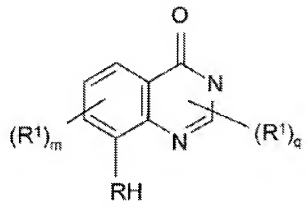
2) Unpredictability in the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved" and

physiological activity is generally considered to be an unpredictable factor. (USPQ 18, 24 (CCPA 1970). See *In re Fisher*, 427 F.2d 833, 839, 166.

Applicants have provided no biological testing of any results where the compositions were combined with these additional "active compounds." Without this, one cannot simply infer that the results of the combination would be additive from the compositions or the active compounds alone. In many instances, the systematic screening of combinations of small molecules can reveal unexpected interactions between the pathways on which they act. (Borisy, et. al., Proceedings of the National Academy of Sciences of the United States of America, 100(13) 7977-7982.)

3) *Number of working examples*. The compound core depicted with specific substituents represent a narrow subgenus for which applicant has provided sufficient guidance to make and use; however, this disclosure is not sufficient to allow extrapolation of the limited examples of compounds to enable the scope of the compositions combined with additional medicament active ingredients. Applicant has provided no working examples of any compositions which have been combined with an additional medicament active ingredient in the present application.

4) *Scope of the claims*. The scope of the claims involves all of the tens of thousands of compositions of the following formula:



whereby the compound above is combined with "an inhibitor of the acetylcholinesterase active site, an antioxidant, an anti-inflammatory agent or an oestrogenic agent," thus the scope of the claims is broad.

5) *Nature of the invention.* The present invention relates generally to neurologically-active compounds, processes for their preparation and their use as pharmaceutical or veterinary agents, in particular for the treatment of neurological conditions, more specifically neurodegenerative conditions such as Alzheimer's disease.

6) *Level of skill in the art.* The artisan using Applicants invention would be a doctor with a M.D. degree, and having several years of professional experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for treating the disease mentioned.

Claim Rejections - 35 USC § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

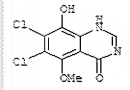
7. Claims 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37 and 39 recite the limitation "R^4 and R^5 are independently selected from H and..." in Claim 37, line 7 and claim 39 line 2. Claims 37 and 39 are dependent from Claim 22, and Claim 22 defines R^4 and does not permit it to be H (see page 19, lines 7-8 of the claims) . There is insufficient antecedent basis for this limitation in the claim. No new matter. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. Claims 22, 26, 35-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Malesani, et. al., Atti - Istituto Veneto di Scienze, Lettere ed Arti, Classe di Scienze Matematiche e Naturali (1973), Volume Date 1972, 131, 9-16. The prior art teaches the following compound which can be seen as example (Vb) on page 10 of the prior art:

RN 57106-52-2 CAPLUS
CN 4(1H)-Quinazolinone, 6,7-dichloro-8-hydroxy-5-methoxy- (9CI) (CA INDEX NAME)



Which is a compound of Claim 22 where m=3, R^1 is -OR^2 where R^2 is a methyl group in the 5-position; Cl in the 6-position; and Cl in the 7-position.

Double Patenting

9. Claims 22, 26-28, 35-39 and 41-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent Publication Application No. 2008/0119470. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent Publication Application No. 2008/0119470 embraces the instant claims 22, 26-28, 35-39 and 41-43 .

The applicants have requested that the double patenting rejection be held in abeyance until the claims are deemed to be in allowable condition.

Allowable Subject Matter

10. Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 40 is free of the prior art. The closest prior art to Claim 40 is Malesani, et. al., cited *supra*, which teaches a quinazolinone compound with a chlorine in the 7-position, but does not teach the other residue groups.

Conclusion

11. Claims 22, 26-28, 35-39 and 41-43 are rejected.

12. Claim 40 is objected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624